

### **REMARKS**

Claims 14 and 15 are currently pending in the application. Claims 14 and 15 are in independent form and have been amended merely to clarify the step of the method. No new matter has been added. Claims 1-13 and 16-32 have been canceled.

Claims 14 and 15 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Meneses, et al. in view of Nohria, et al. Specifically, the Office Action holds that Meneses, et al. teaches a method of immunotherapy to treat H&NSCC comprising administering an effective amount of CY and INDO and a cytokine mixture comprised of IL-1, IL-2, TNF- $\alpha$ , and IFN- $\gamma$ . Meneses, et al. does not teach a cytokine mixture consisting of those cytokines. However, the Office Action holds that it would have been obvious for one skilled in the art to pick those four cytokines with a reasonable expectation of success. The Office Action holds that using cytokines in immunotherapy has long been recognized as part of the ordinary skill in the art as evidenced by Nohria, et al. The Office Action holds that the particular combination of cytokines recited in the instant claims were obvious at the time of the invention given that it is a well-known practice to optimize results. Reconsideration of the rejection under 35 U.S.C. §103(a), as being unpatentable over Meneses, et al. and Nohria, et al. is respectfully requested.

“Any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed”; however, that reason must be present for the combination to be obvious. *KSR Intern Co. v. Teleflex*, 127 S. Ct. 1727, 1742, U.S. (2007). This requirement was confirmed in *Takeda Chem. Indust., et al. v. Alphapharm*, No. 06-1329 (Fed. Cir. 2007).

“The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been

obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007) noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit." MPEP Section 2143.

"The rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art." *KSR International Co. v. Teleflex Inc.*, 83 USPQ2d 1385, 1395 (2007) and MPEP Section 2143.

Meneses, et al. teaches the use of a cytokine mixture that includes IL-1, IL-2, IL-6, IL-8, IL-10, IL-12, TNF- $\alpha$ , CSF, and IFN- $\gamma$ . Meneses, et al. does not express any criticality to any of the cytokines used in the mixture. Furthermore, Meneses, et al. states that IL-2 alone was shown to cause cancer recurrence with little clinical activity. Nohria, et al. also does not state that any particular cytokine is better than another. Thus, comparing the composition of Meneses, et al. versus what was known in the prior art, each of the cytokines would be expected to be necessary to perform a certain function, and each would be expected to be critical to the function of the cytokine mixture. It would not be expected that fewer cytokines would provide as good of a response as the composition of Meneses, et al. especially in view of the fact that IL-2 by itself is detrimental to a patient's health. Therefore, it is unexpected that the critical cytokines of IL-1, IL-2, TNF- $\alpha$ , and IFN- $\gamma$  alone without the presence of other cytokines can be used as an effective treatment for cancer.

Since neither the cited references alone or in combination with knowledge in the art suggest the currently claimed invention, it is consequently respectfully submitted that the claims are clearly patentable over the combination, even if the combination were to be applied in opposition to applicable law, and reconsideration of the rejection is respectfully requested.

Claims 14-15 of this application have further been rejected as unpatentable based on non-statutory obviousness-type double patenting over Patent No. 6,977,072. Claims 14-15 have also been provisionally rejected over USSNs 11/582,063, 11/374,783, 11/337,358, and 11/006,451. As noted in the Office Action, these rejections can be readily overcome by the filing of a terminal disclaimer in compliance with 37 C.F.R. 1.321(c) or (d). Applicant stands ready to provide the appropriate terminal disclaimer upon the indication of the allowance of the pending claims.

The remaining dependent claims not specifically discussed herein are ultimately dependent upon the independent claims. References as applied against these dependent claims do not make up for the deficiencies of those references as discussed above, and the prior art references do not disclose the characterizing features of the independent claims discussed above. Hence, it is respectfully submitted that all of the pending claims are patentable over the prior art.

In conclusion, it is respectfully submitted that the presently pending claims are in condition for allowance, which allowance is respectfully requested. Applicant respectfully requests to be contacted by telephone if any remaining issues exist.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

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/Sherry Kelly/  
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